DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

July 26, 2002

Certified Mail—Return Receipt Requested

Mr. Lloyd Nash, Owner
Lloyd Nash Livestock
PO Box 3064
Cookeville, TN 38502

Warning Letter No. 02-NSV-33

Dear Mr. Nash:

An inspection of your operation located in Cookeville, Tennessee, by our investigator on June 14, 2002 confirmed that two (2) cows purchased by you on or about March 14, 2002 from [redacted] and sold by you on or about March 15, 2002 for slaughter for human food at [redacted], were in violation of Section 402(a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act (the Act).

USDA/FSIS analysis of tissues collected from these animals disclosed the presence of 0.06 and 0.19 parts per million (ppm) penicillin in kidney tissues; 5.95 ppm and 2.68 ppm, 1.12 ppm and 1.39 ppm, 16. 9 ppm and 7.04 ppm tilmicosin in liver, muscle and kidney tissues, respectively; and 1.15 ppm and 0.83 ppm sulfadimethoxine in liver and muscle tissues, respectively. A tolerance of 0.05 ppm has been established for residues of penicillin in edible tissue of cattle (Title 21, Code of Federal Regulations (CFR), Section 556.510). A tolerance of 1.2 ppm in liver tissue has been established for residues of tilmicosin in the target tissue of cattle (Title 21 CFR Section 556.735). There are no established tolerances for tilmicosin in kidney and muscle tissues in target tissue in cattle. In 21 CFR Section 558.618, tilmicosin is limited for use in swine feed only. A tolerance of 0.10 ppm has been established for residues of sulfadimethoxine in edible tissue of cattle (Title 21 CFR Section 556.640). The presence of these drugs in the edible tissue from these animals causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

The violations listed above are not intended to be an all-inclusive list. It is your responsibility to assure that your operations are in compliance with the law. As a dealer of animals, you are frequently the individual who introduces or offers for introduction into interstate commerce the adulterated animals. As such, you share responsibility for violating the Federal Food, Drug, and Cosmetic Act. To avoid future illegal residue violations, you should take precautions such as:

1. implementing a system to determine from the source of the animal whether the animal has been medicated and with what drug(s); and

2. if the animal has been medicated, implementing a system to withhold the animal from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissues. If you do not want to hold the medicated animal, then it should not be offered for human food, and it should be clearly identified and sold as a medicated animal.

You should be aware that it is not necessary for you to have personally shipped animals in interstate commerce to be responsible for a violation of the Act. The fact that you purchased adulterated animals which were subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within fifteen(15) working days of receipt of this letter of the steps you have taken to bring your operation into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,

Howard E. Lewis
Acting Director, New Orleans District

CED:JEH:man

Cc: Stephen Nash, Transportation Director
Lloyd Nash Livestock
PO Box 3064
Cookeville, TN 38502

Enclosures:
21 CFR 556.510
21 CFR 556.735
21 CFR 556.640
21 CFR 558.618